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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,871	08/02/2001	Robert L. Rykhus JR.	687-437	5424

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/920,871	Applicant(s) RYKHUS ET AL.	
	Examiner Michael Thaler	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-23, 25 and 50-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-23, 25 and 50-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/13/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2005 has been entered.

Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789). Hogan discloses a tubular sheath 21 and a walled surface comprised of polydioxanone (col. 2, line 58), the cylindrical sleeve having a limited in vivo lifetime (since it is bioabsorbable) which is controllable as indicated in col. 3, lines 20-23. Further, the in vivo lifetime is inherently "controllable" as claimed since it is controlled or determined at the time of manufacture by factors such as the size of the sleeve, the specific choice of bioabsorbable material, whether or not it is exposed to gamma radiation (and how much), noting that the Hogan stent is inherently capable of being exposed to gamma radiation. Hogan fails to disclose the stent as being annealed. However, Stack teaches that the bioabsorbable filaments of a self-expanding stent should be annealed in order

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to heat set them and thus insure that they will return to a helical form if distorted (page 26, lines 16-18). It would have been obvious to anneal the Hogan filaments so that the Hogan stent too would have this advantage. As to the term "fenestrated" walled surface, the openings between the threads of the Hogan stent are fenestrations, making the wall "fenestrated", as broadly claimed.

Claims 1-3, 8-11, 16, 18-23, 50, 51 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511). Hogan discloses a bioabsorbable self-expanding stent (col. 5, lines 50-66) comprising a cylindrical sleeve (e.g. 21) including a latticed network formed from a plurality of monofilaments 22, 26 braided in an alternating braid pattern (col. 5, lines 49-50) which comprise at least one biocompatible polymer (col. 7, lines 45-50), said cylindrical sleeve having a limited in vivo lifetime (since it is bioabsorbable) which is controllable as indicated in col. 3, lines 20-23. Hogan fails to disclose the stent as being annealed. However, Stack teaches that the bioabsorbable filaments of a self-expanding stent should be annealed in order to heat set them and thus insure that they will return to a helical form if distorted (page 26, lines 16-18). It would have been obvious to anneal the Hogan

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filaments so that the Hogan stent too would have this advantage. Hogan fails to disclose the stent as being gamma-irradiated. However, Cotterman et al. teach that a stent ([0043]) should be irradiated with gamma irradiation in the amount of 39 kGy in order to sterilize it effectively ([0098]). It would have been obvious to irradiate the Hogan stent with this amount of gamma irradiation so that it too would be sterilized. As to claims 20-23, Hogan fails to disclose the specific diameter claimed. However, it was well known in this art to size stents as with the specific diameter claimed so that it fits a correspondingly sized blood vessel. It would have been obvious to size the Hogan stent as claimed so that it would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03). As to claim 57, Hogan discloses poly-L-lactide in col. 2, line 55.

Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claims 1 and 11 above, and further in view of Amstrup (5,476,508). Hogan fails to disclose a single strand shift in the braid. However, Amstrup teaches that braiding in a stent should include a single strand shift (at 12) in order to interlock the

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weave and apparently guarantee a stable crossing region which can accept large restoring forces (col. 4, lines 7-21). It would have been obvious to include a single strand shift in the Hogan braid so that it too would have this advantage.

Claims 5-7 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claims 1 and 9 above, and further in view of Thompson et al. (5,957,974). Hogan fails to disclose the claimed braid angle. However, Thompson et al. teach that the braid angle for a self-expanding stent should be 60-150 and preferably 90-100 degrees (col. 7, lines 21-22) apparently in order to optimize the amount of shortening (col. 7, lines 24-35). It would have been obvious to use this braid angle in the Hogan braid so that it too would have this advantage.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Turnlund et al. (5,629,077). Hogan fails to disclose an under-two-over-two braid pattern. However, Turnlund et al. teach that the braid pattern for a stent should be under-two-over-two (col. 5, lines 54-56) apparently in order to obtain the desired strength of the

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mesh (col. 6, lines 6-9). It would have been obvious to use this braid pattern in the Hogan stent so that it too would have this advantage.

Claims 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Shaolian et al. (6,261,316). Hogan fails to disclose the claimed expansion force of 4, 6, 8 or 10 N or more. However, Shaolian et al. teach, in col. 14, lines 14-31, that the expansion force for a stent prosthesis should be as high as 8 lbs. (about 285 N) apparently in order to adequately expand the stent. It would have been obvious to provide the claimed expansion force for the Hogan stent so that it too would have this advantage.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Bolea (6,063,591). Cotterman et al. disclose sterilization using gamma irradiation or ethylene oxide [0003], but fail to disclose combining these procedures. However, Bolea teaches combining gamma irradiation with ethylene oxide for sterilization purposes (col. 8, line 65 to col. 9, line 2) apparently in order to obtain the advantage

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of insuring the effectiveness of the sterilization. It would have been obvious to combine these sterilization procedures during the Cotterman et al. procedure (incorporated into the Hogan stent) so that it too would have this advantage.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note col. 6, lines 50-57 of Dauner et al. (6,458,148), col. 7, lines 16-24 of Hehnenberger et al. (6,884,394) and col. 22, lines 25-29 of Schwartz et al. (6,869,938).

Applicant's arguments filed June 13, 2005 have been fully considered but they are not persuasive. As to the term "fenestrated", The Meriam-Webster Online Dictionary defines "fenestrated" as "having one or more openings or pores". Applicant's specification describes the open spaces between the braided filaments of the braided stent shown in figures 1A-1C as "openings" ([0034]). Similarly, the open spaces between the braided filaments of the of the Hogan stent may fairly be considered "openings". Since the Hogan stent has "one or more openings", it is "fenestrated" according to the Dictionary definition referred to above. The same dictionary defines "fenestration" as "an opening in a surface (as a wall or membrane)". Although the cylindrical wall of the Hogan stent is formed by braided filaments, it never the less forms a wall or

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surface. Thus, the openings in this wall are fenestrations according to the Dictionary definition referred to immediately above. As further evidence that the meaning of the term "fenestration" is broad enough to include one of the many spaces between braided filaments, note paragraph [0082] of Burke et al. (2005/0033409) which includes the statement "The interwoven support members 24 form a plurality of fenestrations 34.". Although applicant's specification uses the term "openings" rather than "fenestrations" to refer to the open spaces between the braided filaments (paragraph [0034]), the specification does not state that the meaning of the term "fenestration", as used in this application, is to be limited only to the type of openings shown in figure 3 of applicant's drawings. As to the combination of Hogan with Cotterman et al., the motivation for exposing the Hogan stent to gamma irradiation is found in the Cotterman et al. teaching that stents should be exposed to gamma irradiation in order to obtain the advantage of sterilizing them effectively. Although the reason given by Cotterman et al. for exposing a stent to gamma irradiation (sterilization of the stent) is different than reason stated in the instant application (fine tuning the in vivo functional life of the stent), the reason given by a reference for providing a feature may be different than the reason given in the application. As

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to claims 52-55, Shaolian et al. disclose that the stent in the compressed state has a diameter that is half, or less, of the stent in the expanded state (col. 15, lines 23-35). The compression resistance of the Shaolian et al. stent is inherently 8N or more (claim 53) or 10N or more (claim 55) since its expansion force is as high as 8 lbs. (about 285 N).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
6/23/05



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731